

REMARKS

Claims 68, 73-77, 86, 94, 105, 106, 109-112, and 115-134 are pending in the application, claims 95, 107, 108, 113 and 114 being canceled and claims 119-134 being newly added herein. Claims 1-67, 69-72, 78-85, 87-93, and 96-104 were previously canceled. Claims 68, 73, 109, 110, 112, 115-119, 130, 133, and 134 are the only independent claims.

Claims Rejections - 35 U.S.C. § 112

Claims 110 and 111 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular the Examiner maintains that the term “isolated wavelengths” is not included in the original disclosure and therefore that the subject matter of claims 110 and 111 was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention.

Applicant respectfully traverses the rejection of claims 110 and 111 under 35 U.S.C. § 112, first paragraph. The word “isolated wavelengths” is merely an alternative for the term “single wavelengths” which is included in the original disclosure. A single wavelength is an isolated wavelength. A single wavelength is by itself, not included in a range with other wavelengths, isolated. One skilled in the relevant art would understand this.

(Claims 110 and 111 distinguish over McDaniel, because McDaniel is interested only in applying ranges of wavelengths. Where a laser is cited as a possible source of treatment radiation, reference is made to filters for broadening out the wavelength so that

the skin is treated with a “narrowband, multichromatic emissions spectrum.” See col. 18, lines 12-29.)

Claims 73-77, 86 and 94 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that application regards as the invention. In particular, the Examiner contends that the term “more frequently” in claims 73 and 94 is a relative term without bounds, that the phrase “said source of Xray or ultraviolet radiation” in lines 2 and 3 of claim 86 has no antecedent basis.

In response to the rejection of claim 73, that claim has been amended herein to provide a more explicit description of what is meant by the term “more frequently.” The Amendment is founded on Paragraph 0056 of the published application. That paragraph has been amended to provide antecedent support for the more precise language introduced herein.

Applicant respectfully traverses the rejection of claim 94 under 35 U.S.C. § 112, second paragraph, inasmuch as the term “more frequently” does not appear in that claim. Claim 94 states that “said treatment sessions increase in number with increasing frequency or intensity of exposure of said skin surface to UV or Xray radiation.” One of ordinary skill in the art would understand the metes and bounds of claim 94, insofar as it covers the method of claim 68 wherein one increases the number of treatment sessions when the subject skin surface is subjected to increased Xray or ultraviolet radiation exposure.

Claim 86 has been amended to correct the defect in antecedent basis pointed out by the Examiner.

Claims Rejections - 35 U.S.C. §§ 102 and 103

Claims 68, 73-77, 94, 95, and 105-118 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,676,655 to McDaniel.

In response to this rejection of the claims, applicant has amended the independent claims and added new claims to provide a better definition of the invention.

Claims Generally As discussed in prior submissions, applicant's invention pertains in principal part to a ***prophylactic*** method of applying electromagnetic radiation to skin surfaces to reduce, if not eliminate, the incidence or likelihood that those skin surfaces will suffer visible cosmetic damage particularly including radiation dermatitis and poikiloderma respectively caused by exposure to a source of Xray or ultraviolet radiation.

McDaniel is directed almost exclusively to the treatment of existing undesirable skin conditions, whether of a medical or cosmetic nature. The only disclosure of McDaniel pertaining to a prophylactic treatment method is in column 22, line 63, through column 26, line 19. There the treatment is for the prevention of skin ***cancer***, in contrast to applicant's claimed invention. More specifically, the only prophylactic treatment methodology of McDaniel is adapted to prevent ***added*** damage to ***visibly damaged*** skin, only ***after*** UV exposure and with the application of an ***exogenous chromophore***.

To clarify the application of the present invention to only Xray or UV exposure, applicant has amended the previously submitted independent claims to recite that the number of treatment sessions in a given time interval is determined at least in part by the frequency or intensity of exposure to Xray or ultraviolet radiation during that time interval (in claim 73, this limitation is more specifically expressed). (See Paragraph 0056

of the published application for written-description support: one skilled in the relevant art would certainly apprehend that applicant had possession of the invention including this more precisely worded claim limitation.) In the use of applicant's invention pursuant to this amendment to the claims, the frequency of e-m energy application is directly determined by the amount – frequency or intensity – of exposure to the sun or other sources of Xray or UV radiation.

Again, the **only** disclosure of McDaniel that relates to periodically treating the effects of UV exposure with a treatment frequency proportional to the frequency or intensity of exposure is disclosed in column 22, line 63, through column 26, line 19. The last paragraph of this passage, the first full sentence in column 26, in particular discloses a treatment that could take place daily, in the evenings of intense solar exposure. A principal difference between McDaniel's method and applicant's is that McDaniel requires application of an exogenous chromophore – photolyase, the desired effect arising from light-induced activation of the photolyase.

It is to be noted that the exogenous chromophore photolyase **must** be extrinsically applied because, contrary to col. 25, line 25, of that reference, photolyases working as contemplated by McDaniel are **not** native or naturally occurring in human beings. See Wikipedia. See also *Future Oncology*, 2006 April - 2 (2): 191-199 Photolyases: Capturing the Light to Battle Skin Cancer," Garinis, GA et al.; *Cell Mol. Life Sci*, 2006 June; 63 (11): 1266-77, "Light-Driven DNA Repair by Photolyases," Essen LO, Clark T (placental mammals like men and mice do not have the ability to manufacture the photolyase enzyme); *Proc. Natl. Acad. Sci. USA*, vol. 90 pp 4389-4393, May 1993,

“Evidence for Lack of DNA Photoreactivating Enzyme in Humans,” Ywan Seng Li et al.
(most unlikely that humans have DNA photolyase).

To distinguish applicant’s invention over McDaniel, applicant’s amendments include the limitation that applicant’s prophylactic electromagnetic radiation is applied to a skin surface of an individual *in the absence of an applied exogenous chromophore*. This amendment is believed to distinguish over McDaniel since that reference teaches the application, after UV damage, of photolyase in a light-activated method to prevent skin cancer.

The embodiments of McDaniel described in column 22, line 63, through column 26, line 19, which are considered closest to applicant’s invention, are like the rest of McDaniel’s disclosed methodology, in being directed to curative therapy for existing undesirable skin conditions. While the passage alludes to treatment for *preventing* skin cancer, the context is skin that has been severely damaged:

The use of such naturally derived or artificially created or genetically engineered photolyase enzymes or related enzymes or other proteins functioning for DNA or RNA repair have a wide variety of applications. For example, the ability to treat skin damaged by sunlight/ultraviolet light of disease and to repair, reverse, diminish or otherwise reduce the risk of skin cancer could be used either as a therapeutic treatment *or as a preventive measure* for people with severely sundamaged skin, with precancerous skin lesions, or with skin cancer. (Emphasis added).

Again, the preventive therapy involves the use of an exogenous chromophore, specifically photolyase:

Another embodiment involves the use of such a photolyase preparation in the evening after returning from a long day of occupational sun exposure or after an accidental sunburn. A spray or lotion containing the photolyase could be applied and then photorepair/photoreactivation of the acutely damaged DNA in the skin could be performed--and this could be performed with a large beam diameter home therapy unit--of

by a white light source which contained enough of the desired wavelength at the proper parameters to produce this reaction.

As indicated above, applicant has amended the previously submitted independent claims (new claim 119 contains a similarly worded limitation) to recite that the applicant's prophylactic electromagnetic radiation is applied to a skin surface of an individual *in the absence of an applied exogenous chromophore*. This limitation distinguishes McDaniel because the above-described method of McDaniel related to therapeutically treating the effects of sun exposure *requires* the exogenous chromophore photolyase – it is the light activation of the chromophore, which is applied after UV damage, that has the desired therapeutic effects. Although applicant contemplated the possible use of an exogenous chromophore such as porphyrin (claims 113 and 114 are canceled herein), the application also clearly contemplates the absence of an applied exogenous chromophore.

Applicant has further amended the independent claims to recite the “pulses being characterized by pulse parameters including pulse duration and total energy so as to at least reduce the incidence or likelihood of non-cancerous visible damage to the skin including radiation dermatitis, sunburns, and poikiloderma caused by exposure of the individual to Xray or ultraviolet radiation.”

Applicant respectfully submits that this limitation distinguishes further over the teachings of McDaniel. Nowhere does McDaniel discuss the application of light pulses characterized by pulse parameters so as to at least *reduce the incidence or likelihood of non-cancerous visible damage* to the skin including radiation dermatitis, sunburns, and poikiloderma caused by exposure of the individual to Xray or ultraviolet radiation.

As indicated above, McDaniel discloses the application of light pulses to an exogenous chromophore on a skin surface to reduce the likelihood of cancer arising due to UV-induced damage in the skin surface. ***McDaniel does not discuss the prevention of noncancerous UV-induced skin conditions.*** Accordingly, McDaniel does not teach or suggest the application of light pulses with combinations of parameters selected to achieve applicant's prophylactic results.

With reference to the Examiner's remarks on page 2 of the Office Action of 10 September 2008, applicant's method is now positively recited to refer to the parameters of the light pulses that are applied in applicant's method. These parameters are controllable by the person applying the light pulses, so that the selection of the pulse parameters is a manipulative step performed by the user and not merely dependent on how organic tissue reacts to the light pulses.

In the remarks on page 2 of the Office Action of 10 September 2008, the Examiner states that if "a reference provides irradiation of tissue with overlapping parameters, it must inherently yield the same result." Applicant respectfully traverses this assertion. Inherency in this case would require requires that every combination of parameters possible under the teachings of McDaniel would result in applicant's claimed invention. This is obviously not the case, inasmuch as McDaniel contemplates many procedures targeting the destruction of dermal features and the treatment – ***not prevention*** – of conditions such as unwanted hair, skin wrinkles and acne. Such parameter sets can result in tissue destruction that is at odds with applicant's method for stimulating healing processes in the skin. Moreover, there is nothing in McDaniel to lead one of ordinary skill in the art to select pulsed light parameters that at least reduce the

incidence or likelihood of non-cancerous visible damage to the skin including radiation dermatitis, sunburns, and poikiloderma caused by exposure of the individual to Xray or ultraviolet radiation.

In the remarks on page 2 of the Office Action of 10 September 2008, the Examiner points out that the claims do not set forth a step for selection of EMR parameters. Pursuant to the Examiner's point, applicant has amended the independent claims herein to recite a selecting step as part of the light-applying step.

Applicant has further amended the independent claims to more precisely define when the prophylactic electromagnetic energy should be applied. Instead of "prior to, during or after" the Xray or UV exposure, the electromagnetic radiation is applied to the skin surface within a predetermined interval of the exposure. As indicated in some of the new dependent claims, the prophylactic treatment can be within days of the potentially damaging exposure.

Applicant has amended the independent claims to clarify that applicant's prophylactic e-m energy treatment occurs without permanently damaging any skin structures. This is in contrast to the body of prior art on techniques that damage certain skin structures to achieve a desirable effect (wrinkle removal, hair removal, varicose vein removal, etc.).

Claims 68 and 112 Claims 68 and 112 distinguish over McDaniel for reasons discussed above with respect to the previously submitted claims in general. In addition, claims 68 and 112 recite that the pulses of electromagnetic radiation applied to the target skin surface are applied in the absence of visible Xray or ultraviolet radiation damage on that skin surface. In contrast, the only prophylactic treatment methodology of McDaniel

is adapted to prevent *added* damage to *already damaged* skin. (See col. 23, line 19-26.) McDaniel prophylactically treats for potential *future skin cancer only* when the skin tissue has prior damage is subject to skin damage such as sunburn or heavy occupational exposure (first full paragraph in column 26). In fact the skin damage is the trigger for the treatment, the treatment occurring only after the skin damage has been incurred. This particular ground for distinguishing over McDaniel also applies to new independent claim 119.

Claim 109 Claim 109 distinguishes over McDaniel for reasons discussed above with respect to the previously submitted claims in general. In addition, claim 109 recites that the electromagnetic radiation is *broadband* radiation including visible wavelengths as well as infrared wavelengths, between 400 nm and 1200 nm. This limitation serves to additionally distinguish over McDaniel inasmuch as that reference clearly teaches the use of *narrowband multichromatic* radiation. See col. 18, lines 12-29, of the McDaniel reference.

Claim 110 Claim 110 distinguishes over McDaniel for reasons discussed above with respect to the previously submitted claims in general. In addition, claim 110 recites that the applied electromagnetic radiation includes one or more single or isolated wavelengths. This limitation serves to additionally distinguish over McDaniel inasmuch as that reference clearly teaches the use of *narrowband multichromatic* radiation. If a laser (monochromatic) is to be used as the light source, filters *must* be employed to *convert* the single or isolated wavelength of the laser to narrowband multichromatic radiation. See col. 18, lines 12-29, of McDaniel.

Claim 119 As recited in new independent claim 119, a skin treatment method

comprises periodically applying, in temporally spaced treatment sessions, pulses of electromagnetic radiation to a skin surface of an individual in the absence of any visible damage from ultraviolet or Xray radiation along the skin surface. The applying of the electromagnetic radiation includes selecting pulse parameters including pulse duration and total energy so as to at least reduce the incidence or likelihood of non-cancerous visible damage to the skin including radiation dermatitis, sunburns, and poikiloderma caused by exposure of the individual to Xray or ultraviolet radiation. The applying of the electromagnetic radiation to the skin surface in each of the treatment sessions occurs without applying exogenous chromophores to the skin. The applying of the electromagnetic radiation to the skin surface increases the local temperature in skin structures including blood vessel cell walls and keratinocytes in the skin to stimulate a healing response and a release of growth factors and other tissue substances, without permanently damaging any skin structures. The pulses of electromagnetic radiation is characterized by parameters including pulse duration of less than about 2 seconds, wavelength and total energy so selected that the applying of the electromagnetic radiation promotes healthy skin and generates no visible damage such as tanning. The skin surface is subjected to x-rays or ultraviolet radiation within one week of the applying at least one (1) of the temporally spaced treatment sessions.

In contrast to McDaniel, claim 119 requires a selecting of pulse parameters so as to at least reduce the incidence or likelihood of non-cancerous visible damage to the skin including radiation dermatitis, sunburns, and poikiloderma caused by exposure of the individual to Xray or ultraviolet radiation. McDaniel selects pulse parameters to reduce the incidence of cancer only. In further contrast to McDaniel, claim 119 requires that

there be no application of an exogenous chromophore to the skin and that the electromagnetic radiation be applied within one week of subjecting the skin surface to Xray or ultraviolet radiation. An additional difference between claim 119 and the prophylactic pulsed-light treatment of McDaniel is that McDaniel applies pulsed energy to skin that is markedly damaged (col. 23, lines 19-26) while pursuant to the present invention as set forth in claim 119 pulsed e-m radiation is applied to a skin surface that does not display any visible damage from ultraviolet or Xray radiation. For all these reasons, the subject matter of claim 119, and its dependent claims, is neither disclosed nor rendered obvious by McDaniel.

Dependent claims 123 through 125 require the light treatment prior to exposure to UV or X-Ray. In contrast, the method of McDaniel, particularly as disclosed in column 22, line 63, through column 26, line 19, requires the application of radiant treatment energy after exposure.

Claim 130 New claim 130 is directed to a prophylactic skin treatment method comprising periodically applying, in temporally spaced treatment sessions, electromagnetic radiation to a skin surface of an individual, wherein the applications are effectuated at regular intervals of at least weekly regardless of the exposure of the individual to Xray or ultraviolet radiation and regardless of the visible condition of the skin surface. The applying of the electromagnetic radiation includes selecting pulse parameters including pulse duration and total energy so as to at least reduce the incidence or likelihood of non-cancerous visible damage to the skin including radiation dermatitis, sunburns, and poikiloderma caused by exposure of the individual to Xray or ultraviolet radiation. The applying of the electromagnetic radiation to the skin surface increases the

local temperature in skin structures including blood vessel cell walls and keratinocytes in the skin to stimulate a healing response and a release of growth factors and other tissue substances, without permanently damaging any skin structures. The electromagnetic radiation is characterized by parameters including pulse duration, wavelength and total energy so selected that the applying of the electromagnetic radiation promotes healthy skin and generates no visible damage such as tanning.

New independent claim 130 distinguishes over McDaniel in part because that reference applies radiation only as a consequence of and in response to visible skin conditions. The present method as set forth in new independent claim 130 applies light to a skin surface regardless of the visible condition of the skin surface. Moreover, when McDaniel applies electromagnetic radiation for prophylactic purposes in connection with exposure to the ultraviolet light of the sun, the radiation is not applied at regular intervals regardless of the exposure of the individual to Xray or ultraviolet radiation. Instead, McDaniel applies radiation immediately (e.g., in the evenings) after dangerous exposure.

Claim 130 distinguishes over McDaniel for other reasons discussed hereinabove. To wit, McDaniel does not disclose or suggest the applying of the electromagnetic radiation which includes selecting pulse parameters including pulse duration and total energy so as to at least reduce the incidence or likelihood of non-cancerous visible damage to the skin including radiation dermatitis, sunburns, and poikiloderma caused by exposure of the individual to Xray or ultraviolet radiation.

Claim 133 According to new independent claim 133, electromagnetic radiation is applied to a target skin surface within a predetermined interval before or during exposure to Xray or ultraviolet radiation. Pursuant to the teachings of McDaniel, (col. 22

through col. 26) electromagnetic radiation is applied to a target skin surface within a certain interval only after exposure to Xray or ultraviolet radiation.

Claim 134 New independent claim 134 is directed to a skin treatment method particularly for alleviating potential skin problems caused by exposure to an Xray source. The method comprises comprising periodically applying, in temporally spaced treatment sessions, pulses of electromagnetic radiation to a skin surface of an individual, the applying of the pulses including selecting pulse parameters including pulse duration and total energy so as to at least reduce the incidence or likelihood of non-cancerous visible damage to the skin including radiation dermatitis, sunburns, and poikiloderma caused by exposure of the individual to Xray radiation. The applying of the electromagnetic radiation to the skin surface in each of the treatment sessions is effectuated within a predetermined interval of the exposure of the individual to Xray radiation and increases the local temperature in skin structures including blood vessel cell walls and keratinocytes in the skin to stimulate a healing response and a release of growth factors and other tissue substances, without permanently damaging any skin structures. The electromagnetic radiation is characterized by parameters including pulse duration of less than about 2 seconds, wavelength and total energy so selected that the applying of the electromagnetic radiation promotes healthy skin and generates no visible damage such as tanning. The number of the treatment sessions in a given time interval is determined at least in part by the frequency or intensity of exposure to Xray radiation during that time interval.

McDaniel says nothing about Xray radiation. It would not be obvious to one skilled in the art to use the method of McDaniel in treating potential non-cancer skin

problems arising from exposure to Xrays.

The Examiner questions on page 2 of the Office Action that no method step is included pertaining to the (critical?) parameter of how skin characteristics impact the treatment result. Applicant directs the Examiner's attention to col. 9, lines 60-64, of McDaniel:

Generally, one skilled in the art will recognize to choose a light wavelength for treatment in the range of about 300 nm to about 1600 nm based on the absorption spectrum of the chromophore or other light-activated topical composition used.

This paragraph supports applicant's position that the effect of skin characteristics on the selection of parameters and the treatment result is within the skill of the art.


Conclusion

For the foregoing reasons, independent claims 68, 73, 109, 110, 112, 115-119, 130, 133, and 134, as well as the claims dependent therefrom, are deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,
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Dated: 10 March 2009